REMARKS

Claims 1, 4-6, 9-11, and 13-16 are currently pending, with claim 1 being the only independent claim. Claims 1 and 6 are sought to be amended. Support for the amendments can be found in the original claims and the specification. Applicants believe that these amendments do not raise any issue of new matter and their entry is respectfully requested.

I. Amendments to the Specification

The amendments changing the position of the sections "**Field of the Invention**" and "**Related Applications**" are made solely to comply with 37 C.F.R. § 1.78(a)(2)(iii) or (5)(iii) and are not believed to add any new matter.

The text amendments to the "**Related Applications**" section correct typographical errors. Applicants note that these errors are not reflected in either the Official Filing Receipt or in the corresponding Published Application No. U.S. 2004/0157212 A1. Because the benefit and/or priority claims were i) presented upon filing the captioned application, ii) properly identified by the United States Patent and Trademark Office in an Official Filing Receipt, and iii) reflected on the face of the corresponding published application, Applicants believe that a petition under 37 C.F.R. § 1.78(a)(3) or (6) is not necessary. See M.P.E.P., 8th ed., rev. 3, § 201.11(III)(D) and §201.11(V) (August 2005).

The amendment to the specification adding text to the paragraph at page 15 does not constitute new matter. This text was copied nearly verbatim from International Application No. PCT/US03/031901, which is the parent of the captioned application. *See* page 5, line 17 to page 6, line 7 of WO 2004/032959 A2, which is the corresponding published application of the parent international application (a courtesy copy is provided herewith). Applicants note that International Application No. PCT/US03/031901 is incorporated by reference in the captioned specification. *See* page 2 ("**Related Applications**") and page 27, lines 2-5. Applicants also replaced U.S. Application No. 09/493,484 with its corresponding issued patent, i.e., U.S. Patent No. 6,951,650. Finally, Applicants have amended the specification to include the complete

address of the ECACC.

II. Claim Objections

The Examiner has objected to claim 1 and its dependent claims for misspelling "ECACC." Office Action, page 3. This spelling of this term has been corrected and Applicants believe that this objection has been rendered moot. Applicants respectfully request that the Examiner reconsider and withdraw this objection.

III. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written Description Rejections Pertaining to Incorporations by Reference

Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. Office Action, page 3. In particular, the Examiner asserts that "deposited material [ECACC accession no. 99011475] and 75% plaque reduction is not described in the specification." *Id.* at 4. The Examiner also notes that Applicant refers to USSN 09/493,484 (now US Patent 6,951,650), but states that "[t]he attempt to incorporate subject matter into this application by reference to US 6,951,650 is ineffective because incorporations by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter." *Id.* at 4.

Applicants have amended a paragraph in the specification at page 15, as described above. Moreover, Applicants reiterate here that this amendment is believed not to introduce any new matter. Accordingly, Applicants believe that the rejection has been accommodated and is rendered moot. Applicants request that the Examiner reconsider and withdraw the rejection.

B. Enablement Rejection Regarding Biological Deposit

Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Office Action, page 5. In

particular, the Examiner states that

> [t]he specification does not disclose any information about strain 99011475.
>
> When a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the term of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

Office Action, page 5 (emphasis in original).

Applicants respectfully point out that such a statement need not be made by an attorney of record. Rather, the patent regulations provide that a representative registered patent attorney or agent can provide such a statement:

> When a registered patent attorney or patent agent acting in a representative capacity appears in person or signs a paper in practice before the United States Patent and Trademark Office in a patent case, his or her personal appearance or signature shall constitute a representation to the United States Patent and Trademark Office that under the provisions of this subchapter and the law, he or she is authorized to represent the particular party in whose behalf he or she acts. In filing such a paper, the registered patent attorney or patent agent must specify his or her registration number and name with his or her signature. Further proof of authority to act in a representative capacity may be required.

37 C.F.R. § 1.34. The M.P.E.P. reiterates that such statements can be made by a registered patent attorney acting as a representative under 37 C.F.R. § 1.34:

> In accordance with 37 CFR 1.34*, a paper filed by a registered patent attorney or agent in an application in which he or she is not of record *>must< include * his or her *>name< and registration number >with his or her signature<. Acceptance of papers filed in patent applications and reexamination proceedings by registered attorneys and agents upon a representation that the attorney or agent is authorized to act in a representative capacity is for the purpose of facilitating replies on behalf of applicants in patent applications and, further, to obviate the need for filing

> powers of attorney ** in individual applications or patents when there has been a change in composition of law firms or corporate patent staffs. Interviews with a registered attorney or agent not of record will, in view of 35 U.S.C. 122, be conducted only on the basis of information and files supplied by the attorney or agent. A person acting in a representative capacity may not sign >(A)< a power of attorney *>(37 CFR 1.32(b)(4)), (B)< a document granting access to an application >(except where an executed oath or declaration has not been filed, and the patent practitioner was named in the papers accompanying the application papers - 37 CFR 1.14(c)), (C) a change of correspondence address (except where an executed oath or declaration has not been filed, and the patent practitioner filed the application - 37 CFR 1.33(a)), (D) a terminal disclaimer (37 CFR 1.321(b)(1)(iv)), or (E) a request for an express abandonment without filing a continuing application (37 CFR 1.138(b))<.

M.P.E.P., 8th ed., § 402 (October 2005 revision).

The below signed registered patent attorney is authorized to act in a representative capacity for the purpose of facilitating replies on behalf of Applicants in the captioned patent application. Further to 37 C.F.R. § 1.808(a), biological samples corresponding to ECACC accession numbers 99011475, 99011472, 99011473 and 99011474 have been deposited under the terms of the Budapest Treaty. Subject to any contractual arrangements allowed under 37 C.F.R. §1.808(b), all restrictions imposed by the Applicants or Assignee of the captioned matter on the availability to the public of biological samples corresponding to accession numbers 99011475, 99011472, 99011473 and 99011474, deposited with the ECACC (European Collection of Animal Cell Cultures), Centre for Applied Microbiology & Research, Porton Down, Salisbury, Wiltshire SP4 OJG, United Kingdom, will be irrevocably removed upon the granting of the captioned application as a patent.

Accordingly, Applicants believe that this rejection has been overcome and respectfully request that the Examiner reconsider and withdraw the rejection.

C. Enablement Rejection Regarding Claim Scope

Claims 1, 4-6, 9-11 and 13-16 are also rejected because the specification allegedly "does not reasonably provide enablement for a method of propagating *any* avian Reovirus without prior adaptation to Vero cells." Office Action, page 6 (emphasis added). Further, the Examiner states that "the amendment to the claims does not limit the scope of the avian Reovirus to any particular ERS isolate. . . . The scope of the claims includes any ERS isolate, which is not enabled for reasons of record set forth in the previous Office action." *Id.* at page 6. Applicants respectfully disagree and assert that the claims are fully enabled by the specification.

Applicants' claims are not drawn to *any* ERS isolate. Rather, the claims are limited to methods of propagating ERS isolates that i) can multiply on Vero cells to a titer of at least about 3.0 $TCID_{50}$/ml *without prior adaptation,* and ii) belong to a defined antigenic class. This class of ERS isolates is defined in that its members are all able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by the avian reovirus ERS sample which is deposited at the ECACC under accession no. 99011475, of at least 75% in a plaque reduction assay. Moreover, this class is also defined insofar as its members all positively react with polyclonal avian reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474, samples of which are deposited at the ECACC.

Upon reading Applicants' specification, it would be routine for the skilled artisan to practice the claimed method. It would not require undue experimentation for the skilled artisan to determine whether an ERS isolate can multiply on Vero cells to a titer of at least about 3.0 $TCID_{50}$/ml without prior adaptation. Moreover, it would not require undue experimentation for the skilled artisan to propagate ERS isolates according to the claimed method, because such isolates can routinely be identified by their antigenic properties. That is, upon reading Applicants' specification, it would be routine for the skilled artisan to identify an ERS isolate useful in the claimed method that

i) is able to induce antiserum in an animal that causes a 75% reduction in plaque formation caused by the ECACC deposited avian reovirus ERS sample

(accession no. 99011475); and

ii) reacts positively with polyclonal avian reovirus antiserum but not with ECACC deposited monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474.

There is no undue burden for the skilled artisan because the deposited ERS sample (i.e., accession no. 99011475) and hybridoma cells afford the ability to test for these identifying properties.

The limitations pertaining to growth without prior adaptation and identifying antigenic characteristics limit the claim to functional embodiments, serve to provide guidance to the skilled artisan and remove any unpredictability in practicing the claimed method. As the Examiner has acknowledged, "[t]he skill of those in the art is high." Office Action mailed July 22, 2005, page 5. Hence, the skilled artisan will readily be able to test whether any ERS isolate has the above described properties, and will thus be able to practice the claimed method.

Applicants note that the Examiner has relied upon Drastini *et al.* and Nwajei *et al.* to assert that "[t]he state of the art demonstrates that not all avian reoviruses are capable of growing on Vero cells without prior adaptation." Office Action mailed July 22, 2005, page 4. This assertion, however, does not support the enablement rejection. Indeed, Applicants' claimed invention is directed to avian reoviruses capable of growing on Vero cells without prior adaptation. Because of this novel and unobvious aspect of the claimed invention, it is unsurprising that the "state of the art demonstrates that not all avian reoviruses are capable of growing on Vero cells without prior adaptation." (*See also* Applicants' specification at page 4, lines 10-12: "As of 2001, there was no disclosure in the prior art of a reovirus that is able to be propagated in a mammalian cell without adaptation. [Nibert et al., Fields Virology 4: p. 1682 (2001)]." *See also* Applicants' specification at page 5, lines 5-8: "However, to date, no chicken infecting reovirus has been shown to grow on Vero cells, without prior adaptation. Accordingly, the art field is in search of a chicken reovirus that can grow to suitable titers on Vero cells, without prior adaptation.") The Examiner has not provided any evidence that avian reovirus

isolates belonging to the defined (and claimed) antigenic class of avian reovirus ERS isolates would not be capable of growing on Vero cells without prior adaptation. Nor has the Examiner cited any publications describing the claimed subject matter.

In summary, Applicants should not be required to limit their claims to particular ERS isolates. The claims do not encompass an unreasonable number of inoperative viruses as they are limited to a defined antigenic class of avian reovirus ERS isolates that will grow on Vero cells without prior adaptation. Upon reading Applicants specification, it is routine for the skilled artisan to practice the full scope of the claimed invention. Accordingly, Applicants respectfully assert that the claims are enabled by the specification and request that the Examiner reconsider and withdraw the enablement-scope rejection.

D. Written Description Rejections

Claims 1, 4-6, 9-11 and 13-16 are also rejected because the claims allegedly contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action, page 6. Further, the Examiner states that "the amendment to the claims does not limit the scope of the avian Reovirus to any particular ERS isolate. . . . The scope of the claims includes any ERS isolate, for which Applicant has not demonstrated possession for the reasons set forth in the previous Office action." *Id.* at page 7. In the previous Office Action, the Examiner stated the following:

> To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The claims only recite a generic avian reovirus (encompassing all wild-type avian reoviruses) and a function (able to grow on Vero cells to a particular titer).

Office Action mailed July 22, 2005, page 6. Applicants respectfully disagree with the Examiner's

conclusion and assert that the specification provides an adequate written description for the claims.

In contrast to the Examiner's assertion, Applicants claims do not encompass *all* wild-type avian reoviruses. Rather, as described above, the reoviruses are limited to a defined antigenic class of avian reovirus ERS isolates that i) can multiply on Vero cells to a titer of at least about 3.0 $TCID_{50}$/ml without prior adaptation, and ii) are readily identified by their antigenic properties. That is, such ERS isolates are identified by their ability to i) induce antiserum in an animal that causes a 75% reduction in plaque formation caused by the ECACC deposited avian reovirus ERS sample (accession no. 99011475); and ii) react positively with polyclonal avian reovirus antiserum but not with ECACC deposited monoclonal antibodies identified by accession nos. 99011472, 99011473 and 99011474.

Moreover, Applicants are claiming propagation of ERS isolates that are adequately described by the specification in terms of their physical and/or chemical properties, and their functional characteristics. By describing these properties, Applicants' specification discloses to the skilled artisan methods of identifying ERS isolates useful according to the claimed invention, and hence, methods of practicing (i.e., making) the claimed method. Therefore, Applicants' specification demonstrates that Applicants had possession of the claimed methods. Rather than encompassing embodiments not in possession at the time of filing the present application, Applicants claims are limited to the clearly possessed embodiment of propagating a well defined class of avian reovirus ERS isolates having particular serological properties.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the written description rejection of claims 1, 4-6, 9-11 and 13-16.

IV. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In particular, the Examiner asserts that "the phrase 'a sample of which' renders the claim indefinite because it is unclear whether the limitations following the

phrase are part of the claimed invention." Office Action, page 7.

Applicants have amended claim 1 and believe that this rejection is now rendered moot. As explained above, the claimed method pertains to propagating avian reoviruses belonging to a defined antigenic class of avian reovirus ERS isolates that are able to induce antiserum in an animal that causes a 75% reduction in plaque formation caused by the ECACC deposited avian reovirus ERS sample deposited under accession no. 99011475. Accordingly, Applicants believe that this rejection has been rendered moot and request that the Examiner reconsider and withdraw the rejection.

Conclusion

Applicants submit that this application is in condition for allowance, and request that it be allowed. Should the Examiner believe that a conference would be helpful in advancing the prosecution of this application, Examiner is invited to telephone Applicants' attorney at the number below.

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

Respectfully submitted,

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